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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VIRDI, SUNDEEP

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,082

Applicant(s)

FITZGERALD ET AL.

Examiner

Sundeep S Virdi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 15 April 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II claims 17-20 in the reply filed on 7/15/2004 is acknowledged. The traversal is on the ground(s) that Applicant has amended the non-elected Group I claims 10-16 to include all limitations of independent claim 17 and therefore Applicant requests that claims 10-16 be rejoined with claims 17-20. This is not found persuasive because even with the limitations of independent claim 17 added to claims 10-16, the product as claimed can still be used in a materially different process of using that product. The product of claims 17-20 can be used without the steps of cutting and peeling that are present in claims 10-16.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 17, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitehouse et al (4,743,265).

Whitehouse discloses an elongated catheter (18 and 20 together) having a distal end and a proximal end with a catheter handle (14 and 16) secured to the elongated

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catheter member (column 4, lines 34-37) and a platform (12) removably secured to the catheter handle (see figure 3).

With respect to claim 18, Whitehouse discloses the removable platform comprising protruding stabilizers (30a and 30b; column 4, lines 10-14).

With regards to claim 20, Whitehouse discloses the removable platform (12) slidably secured (40a and 40b; column 5, lines 30-53) to the catheter handle (14 and 16).

With regards to claim 24, the elongated catheter member includes an inner member (20) and an outer member (18; column 4, lines 20-22).

With regards to claim 25, the catheter handle (14 and 16) is slideable with respect to the outer member (18; 28a and 28b with 56a and 56b).

With regards to claim 26, the catheter handle includes structure securing the catheter handle to the outer member (28a and 28b with 56a and 56b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Hakky et al (6,113,577).

Whitehouse discloses the claimed invention as discussed above. However, Whitehouse does not teach the lower surface of the platform being curved.

Hakky et al teaches the use of a platform with a curved lower surface (16) in a intravascular access device positioning system in order to make the platform compatible with the patient's skin and to allow a snug fit around a patients limb (column 7, lines 9-12).

It would have been obvious to one of ordinary skill in the art to modify the platform of Whitehouse and curve it as taught by Hakky in order to make the platform compatible with the patient's skin and to allow a snug fit around a patients limb (column 7, lines 9-12).

4. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Burgermeister (2004/0193205).

Whitehouse et al discloses the claimed invention as discussed earlier. However, Whitehouse does not disclose a handle including a knob, which is slideable with respect to the handle and attached to the outer member of a catheter.

Burgermeister disclose an elongated catheter member (10), which includes an inner member (12) and an outer member (27), a catheter handle (14), which is slideable with respect to the outer member (27) and structure (see figure 1) securing the catheter to the outer member (27). Burgermeister further teaches the use of a knob (26), which is slideable with respect to the handle (see "Description of Preferred Embodiment", paragraph 0019) and is attached to the outer member (see figure 1) in order to steer a guidewire that is fed through the catheter (see "Description of Preferred Embodiment", paragraph 0019).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and include a knob that is slideable with respect to the handle and is attached to the outer member of the catheter in order to steer a guidewire that is fed through the catheter.

5. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Burgermeister as applied to claims 27 and 28 above, and further in view of Gellman et al (2002/0055748).

With regards to claim 29, Whitehouse and Burgermeister disclose the claimed invention. However, they do not disclose the catheter handle including a cutter that is configured with an interior of the catheter handle.

Gellman teaches the use of a cutter (1312) configured with an interior of a catheter handle (1320; see "Detailed Description of the Preferred Embodiment, paragraph 0306) in order to cut through tissue that may become disposed between the inner and outer tubes ("Detailed Description of the Preferred Embodiment, paragraph 0306).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter configured within the interior of a catheter handle as taught by Gellman in order to cut through any tissue that may become disposed between the inner and outer tubes of the catheter.

With regards to claim 30, Gellman teaches the use of a cutter that is slideable with respect to the catheter handle (paragraph 0306) so that the cutter can be maneuvered to protrude from the distal tip of the catheter.

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It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter that is slideable with respect to the catheter handle as taught by Gellman so that the cutter can be maneuvered to protrude from the distal tip of the catheter.

With regards to claim 31, Gellman teaches the use of a cutter (1312) that is attached to a knob (1322) in order to engage the cutter with the knob and enable the knob to control the cutter and maneuver it to protrude from the distal tip of the catheter (paragraph 0306).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter attached to a knob as taught by Gellman in order to engage the cutter with the knob and enable the knob to control the cutter and maneuver it to protrude from the distal tip of the catheter (paragraph 0306).

With regards to claim 32, Gellman teaches the use of a slideable cutter attached to a catheter in order to allow the cutter to be maneuvered to protrude from the distal tip of the catheter.

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter slideably attached to the outer member. While Gellman does not teach an outer and inner member, the catheter that has the slideable cutter attached to it in Gellman has the same properties as the outer member of the catheter in Whitehouse and Burgermeister and therefore it would have been obvious to attach the cutter to any type of catheter, be it an inner or outer

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member in order to allow the cutter to be maneuvered to protrude from the distal tip of the catheter as taught by Gellman.

With regards to claim 33, Gellman discloses the use of a cutter that could be configured to longitudinally dissect the outer member of a catheter (1312).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter so that the cutter could be configured to longitudinally dissect the outer member of the a catheter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haindl (4,981,475) discloses a device for fastening a catheter. Bierman et al (5,192,273) discloses a catheterization system. Bierman (5,800,402) discloses a catheter anchoring system and method of use. Cardoso (6,093,169) discloses a nasal oxygen catheter. Gordon (4,224,937) discloses a stabilizing fitting for an intravenous catheter. Lash et al (4,662,873) discloses a n intravenous tube stress relief bracelet. Speaker (4,453,933) discloses an intravenous device. Chi (6,613,014) discloses a catheter hub with a detachable push device. Winston et al (6,752,800) discloses a catheter handle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeep S Virdi whose telephone number is 703-305-0499. The examiner can normally be reached on M-F 9am-5:30p.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sundeep Virdi
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MICHAEL J. HAYES
PRIMARY EXAMINER